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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/488,164	06/07/1995	JOHN J. KOPCHICK	7707-015	8450

1444 7590 06/10/2003

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EXAMINER

SAOUD, CHRISTINE J

ART UNIT PAPER NUMBER

1647

DATE MAILED: 06/10/2003

38

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
08/488,164

Applicant(s)
KOPCHICK et al.

Examiner
Christine Saoud

Art Unit
1647



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 27, 2003
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32, 38, 40-43, 107, 109, 110, and 120-162 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 40-43, 107, 109, 110, 120-138, 140-149, 158, and 161 is/are allowed.
- 6) ☒ Claim(s) 32, 38, 150-157, 159, 160, and 162 is/are rejected.
- 7) ☒ Claim(s) 139 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

DETAILED ACTION

Response to Amendment

1. Amendments to the claims were filed in papers #34, 35, 36 and 37 as follows:

Paper #34: claims 35, 36 and 62 were canceled, claims 10, 29, 66, 81, 88, 89, 107, 108 and 109-112 were amended, and claims 114-117 were added. Paper was filed May 8, 2002.

Paper #35: claims 63 and 88-98 were canceled and claims 107 and 114 were amended. Paper was filed July 25, 2002.

Paper #36: claims 44 and 45 were canceled and claims 118-119 were added. Paper was filed January 7, 2003.

Paper #37: claims 10-31, 33, 34, 37, 39, 65-87, 99-106, 108 and 111-119 were canceled, claim 40 was amended, and claims 120-162 were added.

Claims 32, 38, 40-43, 107, 109-110 and 120-162 are pending in the instant application.

2. It is suggested that in response to this Office action, that a copy of the pending claims be submitted as an appendix so that Applicant and Examiner are clear on which claims are currently pending in the instant application. This is merely to assist in the speedy resolution of this application and to assure that Applicant and Examiner are on the "same page" so to speak with regard to the claims at issue and in view of the numerous amendments in the instant application.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

5. Applicant's arguments filed in the previous papers have been fully considered. However, in light of the new grounds of rejections for some of the claims, they are not persuasive.

Claim Objections

6. Claim 139 is objected to because of the following informalities: claim 139 ends with "and chicken growth hormones" (note the plural nature of hormone). It would appear that this term should be singular since it is recognized that there is only a single factor in each species which is considered growth hormone. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 150-157 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 150 is directed to a nucleic acid molecule which encodes a variant of growth hormone, wherein the variant comprises an amino acid sequence at least 80% identical to a native growth hormone sequence, and where said variant "has an alpha helix which is at least 80% identical, but not completely identical, to the alpha helix of said mammalian growth hormone which corresponds to the third alpha helix of bovine growth hormone". Claims 151-157 depend from claim 150. The instant specification fails to provide a basis for the combination of limitations which are present in claim 150. Such a combination which forms an inventive concept is not present in the instant specification, and is therefore new matter. Applicant asserts that support for the claim is found at page 18, lines 6-10 of the specification. This argument is not persuasive because the combination of 80% identical with the entire molecule as well as 80% within the third alpha helix is not supported. The disclosure relates to percent homology (which we are interpreting as being identity) of (1) 50% corresponding to the third alpha helix, (2) more preferably 80% corresponding to the third alpha helix, and (3) more preferably 80% over the entire length of the polypeptide. Therefore, the combination of being 80% of the whole molecule, with additionally being 80% in the alpha helix is not disclosed, and is new matter. Please see additional 112/2nd rejections of this claimed subject matter below.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 32, 38, 150-157, 159-160, and 162 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 32 and 38 depend from canceled claims. Therefore, it is not clear what is being claimed. Since the subject matter of the base claims has been canceled, It is suggested that these claims also be canceled, which would obviate this ground of rejection.

Claim 150 is directed to a nucleic acid molecule which encodes a variant of growth hormone, wherein the variant comprises an amino acid sequence at least 80% identical to a native growth hormone sequence, and where said variant "has an alpha helix which is at least 80% identical, but not completely identical, to the alpha helix of said mammalian growth hormone which corresponds to the third alpha helix of bovine growth hormone". First, it is not clear if the 80% is just within the alpha helix, or if the 80% is to encompass two different calculations of the alpha helix, and then the rest of the molecule. Second, the specification at page 18, line 9, defines the third alpha helix as being "approximately, residues 106-129". This recitation is vague and indefinite for what would constitute the third alpha helix because "approximately" is not definite, therefore, the metes and bounds of "third alpha helix" are not known. Lastly, the claim recites "the third alpha helix", which does not appear to have antecedent basis in the claim. The first recitation of "alpha helix" does not denote which one, so it is conceivable that any alpha helix is being altered and then compared to the third alpha helix of bovine growth hormone for the basis of % identity? This recitation is confusing, and therefore, indefinite. Claims 151-157 depend from 150, and are therefore, also indefinite.

Claims 159 and 160 recite "at least as large in volume as proline" and "at least as large in volume as leucine". It is acknowledged that the terminology of "at least as large" is present in the specification as originally filed (see page 21), the terminology of "volume" is not present. Additionally, the art does not recognize this terminology in association with amino acid substitutions, and it is therefore, confusing to understand what limitations are placed on the claim. If Applicant is intending substitution with an amino acid other than proline or leucine, then this could be conveyed by just stating that limitation. If Applicant is intending to exclude amino acids from the substitution, than an exclusionary clause could be put in. However, it may mean that other amino acids are intended, and because this type of terminology in combination with amino acids and substitution is not common in the art, the metes and bounds of what is intended are not clear, and the claims are indefinite. If Applicant merely intends that the amino acids be selected from a particular group, while excluding some of the known amino acids, it is suggested that these amino acids be listed in a Markush. Alternatively, if particular amino acids are to be excluded, then this could be accomplished by making this a limitation of the claim. It should be noted, that if Applicant is merely trying to encompass non-naturally occurring amino acids, it should be noted that language of substitution with a different amino acid does not necessarily exclude non-naturally occurring amino acids.

Claim 162 is directed to a method of producing a protein, "which comprises maintaining the cells of claim 154". However, claim 154 is directed to a nucleic acid molecule, and not a cell. Therefore, this claim is indefinite for lack of antecedent basis for "cells of claim 154".

Allowable Subject Matter

11. Claims 40-43, 107, 109-110, 120-138, 140-149, 158, 161 are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Christine J. Saoud, Ph.D., whose telephone number is (703) 305-7519. The Examiner can normally be reached on Monday to Thursday from 8AM to 2PM. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. §§ 1.6(d) and 1.8). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternate number. Official papers filed After Final rejection filed by fax should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

**CHRISTINE J. SAOUD
PRIMARY EXAMINER**

Christine J. Saoud